

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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BROOKE WARREN,

Plaintiff,

- against -

RESMED CORP., and APRIA
HEALTHCARE LLC

Defendants.
----- X

No. 21 Civ. 8531 (JFK)

OPINION & ORDER

APPEARANCES

FOR THE PLAINTIFF

Perry D. Silver & Daniel Benjamin Rubin, SILVER &
KELMACHTER, LLP

FOR THE DEFENDANT RESMED CORP.

Andrew Jonathan Calica, Beth S. Rose, Erin Elizabeth
Barrett, MAYER BROWN LLP

FOR THE DEFENDANT APRIA HEALTHCARE LLC

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JOHN F. KEENAN, United States District Judge:

Plaintiff Brooke Warren ("Plaintiff"), the widower of Philip T. Warren ("Mr. Warren") and the executor of his estate, brings this products liability action against Defendants ResMed Corp. ("ResMed"), Apria Healthcare LLC, and Apria Healthcare Group Inc. (together, "Apria," and collectively, "Defendants"), alleging that Mr. Warren died while using an Astral 150 ventilator, which is manufactured, marketed, and sold by the Defendants. The Plaintiff's amended complaint ("AC") asserts nine claims against the Defendants under New York State law.

Presently before the Court is the Defendants' motion to dismiss four of the Plaintiff's claims pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons set forth below, the Defendants' motion is GRANTED.

I. Background

The following facts are drawn from the AC and assumed to be true for purposes of this motion. See Koch v. Christie's Int'l, PLC, 699 F.3d 141, 145 (2d Cir. 2012). Prior to his death, Mr. Warren suffered from a degenerative neurological disease known as Charcot-Marie-Tooth Type 1A ("CMT 1A"). (AC ¶ 39, ECF No. 24.) In Mr. Warren's case, CMT 1A specifically impacted his peripheral nervous system, including his phrenic nerve, which is responsible for causing the diaphragm to contract and relax and helps control breathing. (Id.) Due to the disease, Mr. Warren occasionally required the help of a ventilator to breath. (Id. ¶¶ 40, 41.) In 2018, Mr. Warren was prescribed an Astral 150 Ventilator by his physician pulmonologist, Dr. David Berlin, to provide non-invasive positive pressure ventilation, oxygen, and carbon dioxide removal. (Id. ¶ 41; Oral Argument Transcript 14:20-23.) Mr. Warren used the ventilator while he slept and periodically during the day. (Id.)

ResMed is a medical equipment company and the manufacturer of the Astral 150. (Id. ¶ 12.) Apria is a home healthcare provider and a retailer of the device. (Id. ¶ 34.) According

to the AC, the Astral 150 is designed and manufactured to activate an audible and visual alarm to alert the user or caretaker to a condition that requires immediate attention, such as "power failures, low pressure, high pressure, low minute ventilation, low respiratory rate, high leak, ventilation stoppage, inoperable internal battery, flow sensor malfunction, and/or power disconnection." (Id. ¶ 48.)

On July 25, 2020, the Plaintiff discovered Mr. Warren unresponsive in their New York City apartment. (Id. ¶ 45.) According to the AC, Mr. Warren was using the Astral 150 before he lost consciousness. (Id.) The AC alleges that when the Plaintiff discovered Mr. Warren, she "observed a gap or opening between the face mask of the [Astral 150] and [Mr. Warren's] face." (Id. ¶ 46.) The AC further alleges that the gap "impaired the functioning of the ventilator in a manner which should have caused an alarm to sound but did not." (Id.) Mr. Warren died shortly after he was discovered by the Plaintiff. (Id. ¶ 124.)

The Plaintiff originally brought this action in the Supreme Court of New York, New York County on August 13, 2021. (Notice of Removal, ECF No. 1.) On October 15, 2021, the Apria defendants, with the consent of ResMed, removed the action to this Court based on federal diversity jurisdiction under 28 U.S.C. § 1332(a). (Id.) The Plaintiff filed the AC on January

12, 2022. Although the AC contains nine enumerated causes of action, it asserts the following eight unique claims against the Defendants under New York law: (1) negligence, (2) strict products liability based on design defect, (3) strict products liability based on manufacturing defect, (4) strict products liability for failure to warn, (5) breach of implied warranty, (6) breach of express warranty, (7) wrongful death, and (8) loss consortium. (AC ¶¶ 50-203.)

The Plaintiff's failure to warn and breach of express warranty claims are based on two documents published and distributed by the Defendants: the "Astral Series User Guide" ("User Guide"), which is published by ResMed, and "The Patient/Caregiver Instruction—Home Ventilator: for Invasive and Non-Invasive Use" ("Patient/Caregiver Instruction"), which is published by Apria. (Id. ¶ 83.) In the AC, the Plaintiff alleges "[u]pon information and belief" that "prior to prescribing the Astral 150 Ventilator to [Mr. Warren], Dr. Berlin was provided with the [User Guide] by Defendant ResMed and [the Patient/Caregiver Instruction] by the Apria [d]efendants." (Id. ¶ 83.) The Plaintiff contends that the warnings contained in the documents were "inadequate and failed to instruct, advise, inform, apprise, or warn Dr. Berlin of the potential risks, complications, malfunction, and faultiness associated with the use of the Astral 150 Ventilator, including

but not limited to internal battery problems, super capacitor leakage, software malfunction, breathing loop malfunction, and sensor malfunction.” (Id.)

As for her breach of express and implied warranty claims, the Plaintiff alleges that the User Guide and Patient/Caregiver Instruction warranted that the “ventilator was fit, was reasonably safe, capable, and was of merchantable quality.” (Id. ¶ 97.) She further alleges “upon information and belief” that Mr. Warren and Dr. Berlin “received, read, and reviewed” the documents and relied on the warranties when prescribing or using the Astral 150. (Id. ¶ 99.) According to the Plaintiff, the documents expressly warranted, among other things, that an “internal battery” in the device would provide “continuous power supply [if] main power is disrupted” and “audible and visual alerts” would activate “without delay” in the event of a malfunction. (Id. ¶ 103.)

The Defendants filed the instant motion to partially dismiss the AC on February 2, 2022. (Mot. to Dismiss, ECF No. 25.) In their motion, the Defendants move to dismiss the Plaintiff’s claims for failure to warn and breach of express warranty pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted.¹

¹ At Oral Argument, the Court asked the Plaintiff’s counsel if the AC asserts a failure to warn claim under a negligence theory. (Oral

(Defendant's Joint Memorandum of Law in Support ("Mem. of L."), ECF No. 26.) The Plaintiff filed a declaration in opposition ("Opposition") to the Defendants' motion on March 9, 2022. (Decl. in Oppo., ECF No. 30.) The Defendants filed a reply brief ("Reply") on March 30, 2022. (Reply, ECF No. 31.) At the request of the Defendants and the Plaintiff, the Court heard oral argument on the instant motion on May 10, 2022.

II. Discussion

A. Applicable Law

To survive a Rule 12(b)(6) motion to dismiss, a "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is facially plausible when a "plaintiff pleads factual content that allows the court to draw the reasonable inference that the

Argument Transcript at 19:6-8, ECF No. 33.) Plaintiff's counsel responded in the affirmative but stated that he could not identify where in the AC the claim is alleged. (Id. 19:11.) During rebuttal, counsel for the Defendants stated that, in his view, the AC only alleges failure to warn under a strict liability theory. (Id. 20:2-4.) The Court posed this question to the parties because the AC, read in a light most favorable to the Plaintiff, appears to assert a failure to warn claim under a negligence theory. (See AC ¶ 53.) The Court, therefore, will treat the Defendants' motion as a motion to dismiss all of the Plaintiff's failure to warn claims. The Court notes that under New York law, "[f]ailure to warn claims are identical under strict liability and negligence theories of recovery." DiBartolo v. Abbott Lab'ys, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (quoting Lewis v. Abbott Lab'ys, No. 08 Civ. 7480 (SCR), 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009)).

defendant is liable for the misconduct alleged.” Id. The plausibility standard “does not impose a probability requirement at the pleading stage; it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal” conduct. Twombly, 550 U.S. at 545. “Conclusory allegations or legal conclusions masquerading as factual conclusions[,]” however, are insufficient “to defeat a motion to dismiss.” Kirch v. Liberty Media Corp., 449 F.3d 388, 398 (2d Cir. 2006) (citation and internal quotation marks omitted).

The Second Circuit has recognized that “[t]he Twombly plausibility standard . . . does not prevent a plaintiff from pleading facts alleged ‘upon information and belief’ where the facts are peculiarly within the possession and control of the defendant . . . or where the belief is based on factual information that makes the inference of culpability plausible.” Arista Recs., LLC v. Doe 3, 604 F.3d 110, 120 (2d Cir. 2010) (cleaned up). A plaintiff cannot, however, “merely plop ‘upon information and belief’ in front of a conclusory allegation and thereby render it non-conclusory.” Citizens United v. Schneiderman, 882 F.3d 374, 384 (2d Cir. 2018). Factual allegations made on information and belief must “be accompanied by a statement of the facts upon which the belief is founded.” Negrete v. Citibank, N.A., 187 F. Supp. 3d 454, 461 (S.D.N.Y. 2016) (internal quotation omitted), aff’d, 759 F. Appx. 42 (2d

Cir. 2019); see also Munoz-Nagel v. Guess, Inc., No. 12 Civ. 1312 (ER), 2013 WL 1809772, *3 (S.D.N.Y. Apr. 30, 2013) ("Though a plaintiff may plead facts alleged upon information and belief where the belief is based on factual information that makes the inference of culpability plausible, such allegations must be accompanied by a statement of the facts upon which the belief is founded.").

B. Application

In the instant motion, the Defendants argue that the AC fails to state a claim for failure to warn and breach of express warranty because the facts alleged "upon information and belief," such as whether Dr. Berlin received and reviewed warnings and instructions from the Defendants regarding the Astral 150, are not "peculiarly within the possession and control of the defendant" and the AC does not contain a statement of "facts upon which the belief[s] [are] founded." (Mem. of L. at 1 (quoting JBCHoldings NY, LLC v. Pakter, 931 F. Supp. 2d 514, 527 (S.D.N.Y. 2013).) The Defendants contend that "absent such a factual basis," the relevant allegations are "purely speculative and cannot provide a basis for" the Plaintiff's failure to warn and breach of express warranty claims. (Id. at 7.) In response, the Plaintiff argues that the facts alleged "upon information and belief" are adequately pled because they are supported by factual assertions contained in

the AC. In the alternative, the Plaintiff requests that she be granted leave to amend the AC in order to include additional facts in support of her allegations made "upon information and belief." The Court addresses the sufficiency of the Plaintiff's failure to warn and breach of express warranty claims in turn.

1. The AC Fails to State a Claim for Failure to Warn

To state a claim for strict liability failure to warn under New York law, a plaintiff must show: "(1) a manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) the failure to do so was the proximate cause of harm." See SUEZ Water New York Inc. v. E.I. du Pont de Nemours & Co., No. 20 Civ. 10731 (LJL), 2022 WL 36489, at *31 (S.D.N.Y. Jan. 4, 2022). In the context of a medical device, a manufacturer or distributor satisfies its duty to warn by "providing information to the prescribing physician." Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). Accordingly, a plaintiff cannot succeed on a failure to warn claim absent proof that the physician did not receive "adequate warnings." Tears v. Bos. Sci. Corp., 344 F. Supp. 3d 500, 511 (S.D.N.Y. 2018).

Here, the AC fails to state a claim for failure to warn because it does not plausibly allege that Dr. Berlin received inadequate warnings from the Defendants. As noted above, the Plaintiff alleges "[u]pon information and belief" that "Dr.

Berlin was provided with the [User Guide] . . . and [the Patient/Caregiver Instructions]" and "[t]he warnings contained therein were inadequate." (AC ¶ 83.) Although the AC is replete with factual allegations concerning the substance of the allegedly "inadequate" warnings, it does not identify a single fact that supports the Plaintiff's "belief" that Dr. Berlin received the documents in question. As a result, the Plaintiff's allegation that Dr. Berlin received the relevant warnings from the Defendants is "wholly conclusory," Twombly, 550 U.S. at 561, and fails "to make[] the inference of culpability plausible[,]" Arista Recs., 604 F.3d at 120. Because the Plaintiff does not adequately allege that Dr. Berlin received the relevant warnings, the AC fails to state a claim for failure to warn. See Gioia v. Janssen Pharms., No. 19 Civ. 04629 (JMA), 2021 WL 5447330, at *2 (E.D.N.Y. Nov. 22, 2021) (dismissing failure to warn claim where plaintiff "fail[ed] to plead what warnings were given to her physician"); Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co., 505 F. Supp. 3d 137, 156 (N.D.N.Y. 2020) (dismissing failure to warn claim where plaintiff failed to "allege any specific facts regarding what warnings, if any, were provided with the [product], and why such warnings were inadequate" (emphasis in original)).

2. The AC Fails to State a Claim for Breach of Express Warranty

The AC also fails to allege sufficient facts to state a claim for breach of express warranty. To state a claim for breach of an express warranty, a plaintiff must show "(1) the existence of a material statement amounting to a warranty, (2) the buyer's reliance on this warranty as a basis for the contract with the immediate seller, (3) breach of the warranty, and (4) injury to the buyer caused by the breach." Goldemberg v. Johnson & Johnson Consumer Cos., 8 F. Supp. 3d 467, 482 (S.D.N.Y. 2014). If the claim involves a medical device, the plaintiff must "allege where, when or how the alleged promise or statement was provided to [the plaintiff] or [their] physicians." Fisher v. APP Pharm., LLC, 783 F. Supp. 2d 424, 431 (S.D.N.Y. 2011); see also O'Neil v. Argon Med. Devices, Inc., No. 317 Civ. 640 (DNH) (TWD), 2020 WL 1149904, at *8 (N.D.N.Y. Feb. 13, 2020) (dismissing express warranty claim because "[p]laintiff does not allege that either he or any of his healthcare providers actually received a copy of [the alleged warranty], much less that he specifically relied on its statement . . ."), report and recommendation adopted, No. 317 Civ. 640 (DNH) (TWD), 2020 WL 1140511 (N.D.N.Y. Mar. 9, 2020).

In the instant motion, the Defendants argue that the AC fails to adequately plead two elements: "the existence of a material statement amounting to a warranty" and "reliance on the warranty." (Mem. of L. at 7-8.) In response, the Plaintiff

argues that it would be “counterintuitive to assume that [1] the written materials accompanying the medical device at issue were not both obtained by or given to the prescribing doctor, and read; and [2] the prescribing doctor did not rely upon the warnings and warranties.” (Decl. in Oppo. at 8.) The Plaintiff also argues that dismissal of her breach of express warranty claims at this stage of the litigation would be “premature” because Dr. Berlin “will be deposed during the course of discovery and [the] [D]efendants can question him at length as to the warranties reviewed and relied thereupon.” (Decl. in Oppo. at 13-14.) In support of this argument, the Plaintiff cites a document included as an exhibit to her Opposition. (Id. at 14.) The document, which is titled “progress note,” appears to be a note written by a nurse practitioner, Elizabeth Kavanaugh (“Kavanaugh”), following a meeting with Mr. Warren. (Decl. in Oppo., Exhibit 1.) In the note, Kavanaugh states: “It is critical for Mr. Warren to continue this mode of ventilation. See Attachment in media for downloaded usage of NIV, patient is 100% compliant.” (Id.) The Plaintiff contends that the document demonstrates that Dr. Berlin received and reviewed “relevant paperwork” associated with the Astral 150. (Id. at 14.)

As noted above, the Plaintiff alleges “upon information and belief” that Mr. Warren and Dr. Berlin “received, read, and

reviewed” the documents produced by the Defendants. (AC ¶ 99.) She also alleges, “upon information and belief[,]” that Dr. Berlin relied on the “express warranties stated [in the documents] prior to prescribing the Astral 150” to Mr. Warren. (Id.) The AC is bereft, however, of any facts “that would permit the inference that [the] Plaintiff actually read these [documents] and directly relied upon them when making the decision to utilize [the Defendants’] product.” Oden v. Bos. Sci. Corp., 330 F. Supp. 3d 877, 895 (E.D.N.Y. 2018), adhered to on reconsideration, No. 18 Civ. 0334 (SJF)(SIL), 2019 WL 1118052 (E.D.N.Y. Mar. 11, 2019); see also Teixeira v. St. Jude Med. S.C., Inc., 193 F. Supp. 3d 218, 225 (W.D.N.Y. 2016) (dismissing express warranty claim where “Plaintiff has not pleaded any facts regarding where, when, and how the alleged statements and promises regarding the [product] were made to him or his physicians by a representative of [the Defendant]” (emphasis in original)). Moreover, the Plaintiff’s argument that it would be “counterintuitive to assume” that Dr. Berlin did not receive and rely on the documents is conclusory and is not a substitute for adequately alleged facts. See Morana v. Park Hotels & Resorts, Inc., No. 20 Civ. 2797 (RA), 2021 WL 1164010, at *3 (S.D.N.Y. Mar. 26, 2021) (“A conclusory allegation made on information and belief is insufficient to make a claim plausible where the complaint’s factual allegations

do not raise a right to relief above the speculative level."). Because the Plaintiff's allegation that Dr. Berlin received and relied on the documents in question is not "accompanied by a statement of the facts upon which the belief is based[,]" the AC fails to state a claim for breach of express warranty as a matter of law. DiVittorio v. Equidyne Extractive Indus., Inc., 822 F.2d 1242, 1247 (2d Cir. 1987); see also Singa v. Corizon Health, Inc., No. 17 Civ. 4482 (BMC), 2018 WL 324884, at *4 (E.D.N.Y. Jan. 8, 2018) ("Alleging something 'upon information and belief' does not suffice to allege a fact under Iqbal and Twombly unless plaintiff can point to some facts that make the allegations more than pure speculation.").

Finally, the Plaintiff's arguments regarding the prospect of future discovery and the substance of the "progress note" are meritless. First, "[a] plaintiff who has failed adequately to state a claim is not entitled to discovery." Main St. Legal Servs., Inc. v. Nat'l Sec. Council, 811 F.3d 542, 567 (2d Cir. 2016); see also Podany v. Robertson Stephens, Inc., 350 F. Supp. 2d 375, 378 (S.D.N.Y. 2004) ("[D]iscovery is authorized solely for parties to develop the facts in a lawsuit in which a plaintiff has stated a legally cognizable claim, not in order to permit a plaintiff to find out whether he has such a claim." (citation omitted)). Second, a plaintiff "may not shore up a deficient complaint through extrinsic documents submitted in

opposition to a defendant's motion to dismiss." Madu, Edozie & Madu, P.C. v. SocketWorks Ltd. Nigeria, 265 F.R.D. 106, 122-23 (S.D.N.Y. 2010) (collecting cases). Lastly, even if the Court were to consider the extrinsic exhibit, it is unclear how the document supports the Plaintiff's "belief" that Dr. Berlin read, reviewed, and relied on the User Guide and Patient/Caregiver Instructions. The note was authored by a nurse practitioner, not Dr. Berlin, and it only demonstrates that Dr. Berlin directed Mr. Warren to employ a "particular mode of ventilation" when using the Astral 150. The document does not refer to the Defendants' materials and it does not support the Plaintiff's assertion that Dr. Berlin relied on the materials when prescribing the ventilator.

Because the AC does not plausibly allege that Dr. Berlin received and reviewed the User Guide and Patient/Caregiver Instructions, the Plaintiff's breach of express warranty claims must be dismissed.

3. Leave to Amend

As noted above, the Plaintiff seeks leave to amend the AC to plead additional facts in support of her claims for failure to warn and breach of express warranty. Federal Rule of Civil Procedure 15(a)(2) directs that leave to amend should be "freely granted" in the absence of "undue delay, bad faith" or "futility of amendment." Foman v. Davis, 371 U.S. 178, 182 (1962).

Amendment is not warranted, however, "absent some indication as to what [a plaintiff] might add to [its] complaint in order to make it viable." Shemian v. Research In Motion Ltd., 570 F. App'x 32, 37 (2d Cir. 2014) (summary order) (quoting Horoshko v. Citibank, N.A., 373 F.3d 248, 249 (2d Cir. 2004) (per curiam)). Thus far, the Plaintiff has not identified what new information she would include in a second amended complaint. The Court will allow the Plaintiff, however, to file a motion for leave to amend the AC within 30 days of this order. Such a motion should include (1) a proposed second amended complaint and (2) a memorandum of law of no more than fifteen pages explaining how the second amended complaint would survive a comparable motion to dismiss brought by the Defendants. The Defendants' opposition brief, which shall not exceed fifteen pages, is due thirty days after the Plaintiff's documents are filed. The Plaintiff's reply brief, which shall not exceed ten pages, is due seven days after the Defendants' opposition is filed.


III. Conclusion

For the reasons set forth above, the Defendants' motion to partially dismiss the Plaintiff's Amended Complaint is GRANTED. The Plaintiff's claims for failure to warn and breach of express warranty contained in Counts One, Two, Three, Six, and Seven of the Amended Complaint are DISMISSED without prejudice. As noted above, the Plaintiff must file her motion for leave to amend the

Amended Complaint within thirty days of this Opinion and Order.
The Clerk of Court is respectfully directed to terminate the
motions docketed at ECF Nos. 20 and 25.

SO ORDERED.

Dated: New York, New York
June 28, 2022



John F. Keenan
United States District Judge